

Financial Conflict of Interest (fCOI) – HSPH Cheat Sheet

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HELPFUL LINKS

Federal PHS regulation: <http://grants.nih.gov/grants/policy/coi/>
 Harvard policy: <https://vpr.harvard.edu/pages/financial-conflict-interest-policy>
 Harvard Chan implementation: <https://www.hsph.harvard.edu/faculty-affairs/outside-activities/implementation-plan/>
 Harvard disclosure system: <https://fcoi.harvard.edu/>
 HCSRA fCOI business process: https://hcsra.sph.harvard.edu/files/hcsra/files/fcoi_hsph_process_document.pdf
 Link to HCSRA fCOI forms and Training: <https://hcsra.sph.harvard.edu/forms>
 PHS+ sponsors: https://vpr.harvard.edu/files/ovpr-test/files/agencies_and_organizations_following_the_phs_fcoi_regulations.pdf
 FDP fCOI Institutional Clearinghouse site: <http://thefdp.org/default/fcoi-clearinghouse/>

DEFINITION OF INVESTIGATOR

Investigator means the project director or principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded or proposed for funding by the NSF or any agency that follows 42 CFR Part 50, Subpart F (see the updated listing at the FDP fCOI link, above). This may include, for example, collaborators or consultants.

Who determines Investigator? PI determines which researchers are Key and PHS investigators *Exception:* If sponsor instructions state that a role *must be Key*, list that person as Key and an Investigator. For example, for NIH mentored career development awards, mentors and co-mentors should be identified as senior/key personnel, even if they are not committing any specified measurable effort per NIH 424 instructions.

WHAT DO I DO?

PHS +		Non PHS +
Proposal Stage	Award Stage	Proposal & Award Stage
<p>All investigators (SPH & other institutions) must have current disclosure on file (less than 1 year old). ---<i>Consultants</i> will fall under SPH’s policy if they are investigators. --<i>“Billing Agreements Out”</i>—See below -if sub institution is in the FDP Clearinghouse, note in the Approval comments and change status to N/A.</p> <p>*Training not required.</p> <p><u>Acceptable approval statuses in GMAS:</u> Needs Review No Interests Reviewed – no conflict Eliminated or Managed Under Review Disclosure on file N/A</p> <p><u>Not acceptable, needs action:</u> No Disclosure Check status</p>	<p>All investigators (SPH & other institutions) must have current disclosure, be trained and <i>must not be in</i> “Needs Review”, “No Disclosure”, “Check status” or “Disclosure on file” status.</p> <p>*Training required.</p> <p><u>Acceptable approval statuses in GMAS:</u> No Interests Reviewed – no conflict Eliminated or Managed N/A</p> <p><u>Not acceptable – needs action:</u> Needs Review No Disclosure Under Review Check status Disclosure on file</p>	<p>Only SPH Faculty and <u>Academic appointments</u> must have current disclosure on file (within current calendar year as per SPH & HU policy).</p> <p>Awards are not held up if fCOI Approval is in “Needs Review” status.</p> <p>*Training not required.</p>

SPH INVESTIGATOR NEEDS REVIEW—What to do

- a) Either an automatic e-mail is sent to Angela Brazeau from GMAS **OR** SRA e-mails Angela with request for review for non competing renewals. Include name of person to be reviewed and GMAS fund/project #. TURAROUND TIME is 1 day. Check in with Angela if more than a few days.
- b) Angela e-mails SRA that review is complete and approval is in correct status.

TRAINING—What to do

For Harvard academic employees, training now occurs in the fCOI reporting system and is mandatory prior to completing a disclosure. You do not need to verify training.

For consultants, training is a link included in the disclosure form that they have to review.

See **“WHAT TO DO IF IT’S A SUBCONTRACTOR INVESTIGATOR”** below for additional information.

HMS INVESTIGATOR IS ON A PROPOSAL OR AWARD

- a) SRA can see the investigator is HMS by observing if they are part of the fCOI system in the GMAS fCOI approval and confirming they are from HMS in their person profile.
- b) E-mail Angela to ask HMS for desired information (include name and GMAS project ID).
- c) SRA or Angela changes approval in GMAS once response is received.

SUBCONTRACTOR INVESTIGATOR

- a) SRA checks to make sure they are part of FDP clearinghouse. If other institution is in the FCOI Institutional Clearinghouse, note in the Approval comments and change status to N/A.
- b) If not part of clearinghouse, send them HSPH [fCOI Form \(For Subcontractors Not Part of FDP\)](#) 1 pager to complete or check Statement of Intent to see if sub certified they have an fCOI policy.

--Sub has their own fCOI policy:

*Save form or signed SOI in GMAS approval; suggest they register in FDP clearinghouse and stop here.

--Sub does not have its own FCOI policy and will rely on Harvard Chan’s:

*For **Training**, they will be directed to complete Training via a link on the form.

*Save completed form in GMAS fCOI approval repository.

OTHER SIGNIFICANT CONTRIBUTOR, CONSULTANT, MENTOR, INVESTIGATOR WHO IS NOT PART OF A SUBCONTRACT

- a) Its worth asking the department if they should really be classified as an investigator.
- b) If they are, they fall under our policy because their institution will not be reviewing the proposal/award.
- c) Send them the detailed HU fCOI disclosure form, [fCOI Form \(Non HU Investigators Excluding Subcontractors\)](#), to fill out. If they indicate an interest, send e-mail to Angela to request review. Save form in GMAS fCOI approval. This form only needs to be signed by the individual (no institutional signature is required).

TRAINING GRANTS—What roles should be classified as an investigator?

We look at what individuals actually do on the project, rather than their title or position. If they are independently responsible for design, conduct or reporting – they would be an investigator. It’s a case by case determination made by the PI.

BILLING AGREEMENTS—Who is responsible for fCOI?

The Prime Awardee is responsible for collection of Conflict of Interest assurances for individuals paid under a billing agreement who are responsible for the design, conduct or reporting of the research

--“billing agreements in”, we are not responsible

--“billing agreements out”, we are responsible and need to check fCOI. Contact Angela and she will try to obtain the disclosure from their prime institution rather than having them disclose here.